

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 2005N-0425]**

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	DDM

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions—(OMB Control Number 0910-0183)—Extension**

The Administrative Procedures Act (5 U.S.C. 553(e)), provides that every agency shall give an interested person the right to petition for issuance, amendment, or repeal of a rule. Under part 10 (21 CFR part 10), § 10.30 sets forth the format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (submission of documents to the Division of Dockets Management (DDM)), a citizen petition requesting the Commissioner of Food and Drugs (the Commissioner) to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. Respondents are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions or groups.

Section 10.33, issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may request reconsideration of part or all of a decision of the Commissioner in a petition submitted under § 10.25 (initiation of administrative proceedings). A petition for reconsideration must contain in a well-organized format a full statement of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were

not previously or not adequately considered by the Commissioner. The respondent must submit a petition no later than 30 days after the decision has been made. However, the Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided in the request to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions who are requesting a reconsideration of a matter from the Commissioner.

Section 10.35, issued under section 701(a) of the act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (submission of documents to DDM), the Commissioner to stay the effective date of any administrative action.

Such a petition must provide the following information: (1) The decision involved; (2) the action requested, including the length of time for which a stay is requested; and (3) a statement of the factual and legal grounds on which the interested person relies in seeking the stay. FDA uses the information provided in the request to determine whether to grant the petition for a stay of action. Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action.

Section 10.85, issued under section 701(a) of the act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (submission of documents to the DDM), an advisory opinion from the Commissioner on a matter of general applicability. An advisory opinion

represents the formal position of FDA on a matter of general applicability. When making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested, and a full statement of the facts and legal points relevant to the request. Respondents to this collection of information are interested persons seeking an advisory opinion from the Commissioner on the agency's formal position for matters of general applicability.

In the **Federal Register** of November 16, 2005 (70 FR 69574), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	156	3	468	12	5,616
10.33	10	2	20	10	200
10.35	13	2	26	10	260
10.85	2	1	2	16	32
Total					6,108

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: **FEB 06 2006**

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February 6, 2006.

*Jeffrey Shuren*

Jeffrey Shuren,  
Assistant Commissioner for Policy.

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